Sic 3840

ROUTING RECORD

DATE	FROM	TO	ACTION
9-30-91	SKT	AKS	P/C
AUG 4 '93	AT	GT	TRANSPOR
8-13-93	JMT	CHJ	TRANSFER
1-19-96	JMT	GCR	~~Transfer~~
3-18-97	GCR	JMT	Cancel (Inactive Status).
3-25-97		→	RECORDS

REFERENCE TO OTHER APCD RECORDS INCLUDING VARIANCES:

085085

4
49

3/18/97
CANCELLED

247254

OCT 1 '91

CAPPS

APPLICATION FOR PERMIT TO CONSTRUCT AND PERMIT TO OPERATE

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

9150 Flair Drive, El Monte, CA 91731

FORM 400A

NC/NOV NUMBER ____
INSPECTOR ____ SECTOR ____
ISSUE DATE ____

COMPANY INFORMATION

LEGAL NAME OF APPLICANT: Pacesetter Systems, Inc.

[X] IRS OR [ ] S.S. NUMBER: 9 5 3 9 8 4 1 4 8

PERMIT TO BE ISSUED TO: (SEE INSTRUCTIONS) Pacesetter Systems, Inc.

BUSINESS MAILING ADDRESS: 12884 Bradley Avenue, Sylmar, CA 91342

TYPE OF ORGANIZATION
[X] CORPORATION
[ ] INDIVIDUAL
[ ] LIMITED PARTNERSHIP
[ ] GENERAL PARTNERSHIP
[ ] GOVERNMENT ENTITY
[ ] OTHER ____

ARE YOU A SMALL BUSINESS? (SEE INSTRUCTIONS) [ ] YES [X] NO

AVERAGE ANNUAL GROSS RECEIPTS: 200 M
NUMBER OF EMPLOYEES: 800

IS YOUR BUSINESS 51 PERCENT OR MORE WOMAN/MINORITY OWNED? (OPTIONAL) [ ] YES [X] NO

ARE ALL FACILITIES UNDER SAME OWNERSHIP IN CALIFORNIA IN COMPLIANCE WITH FEDERAL, STATE AND LOCAL AIR POLLUTION CONTROL RULES? [X] YES [ ] NO

ARE YOU THE OWNER OF THE EQUIPMENT UNDER THIS APPLICATION? [X] YES [ ] NO

[ ] IRS OR [ ] S.S. NUMBER OF THE OWNER

IF NO, ENTER LEGAL NAME OF OWNER

FACILITY INFORMATION

EQUIPMENT ADDRESS/LOCATION: 15900 Valley View Court (NUMBER / STREET)
Sylmar (CITY OR COMMUNITY), CA, 91342 (ZIP CODE) * 91341

FACILITY NAME: Pacesetter Systems, Inc.

FACILITY ID NUMBER (SEE INSTRUCTIONS): 0 8 5 0 8 5 4/12/91

CONTACT PERSON AND TITLE: Stephen R. Walters, AQC Inc.

CONTACT TELEPHONE NUMBER: (714 894-5252

NUMBER OF EMPLOYEES AT THIS FACILITY: 800

TYPE OF BUSINESS AT THIS FACILITY: Pacemaker Manufacturing

BUSINESS TYPE CODE (SEE INSTRUCTIONS): 3 8 4 0

IS THERE A SCHOOL WITHIN 1,000 FEET OF YOUR PROPERTY? YES [ ] NO [X]

EQUIPMENT INFORMATION

EQUIPMENT DESCRIPTION (SEE INSTRUCTIONS): Ethylene Oxide Sterilizer #1, Getinge Model 8440AR1 (refer to supplemental for additional information)

APPLICATION FOR: (SEE INSTRUCTIONS)
[X] NEW CONSTRUCTION
[ ] EXISTING EQUIPMENT OPERATING WITHOUT PERMIT
[ ] EXISTING EQUIPMENT WITH EXPIRED PERMIT
[ ] MODIFICATION
[ ] CHANGE OF PERMITTEE
[ ] CHANGE OF LOCATION
[ ] CHANGE OF PERMIT CONDITION

ARE YOU SUBMITTING MULTIPLE APPLICATIONS FOR EQUIPMENT IDENTICAL TO THAT DESCRIBED ABOVE? [ ] YES [X] NO

HAVE YOU BEEN ISSUED A NOTICE TO COMPLY (NC) OR A NOTICE OF VIOLATION (NOV) FOR THIS EQUIPMENT? [ ] YES [X] NO

NC NUMBER: NOV NUMBER: NOTICE ISSUE DATE:

NUMBER OF EMPLOYEES NEEDED TO OPERATE THIS EQUIPMENT: 1

IF THE EQUIPMENT HAS A PREVIOUS WRITTEN PERMIT, STATE NAME OF PERMITTEE:
PREVIOUS PERMIT NUMBER:

FOR NEW CONSTRUCTION OR MODIFICATION, ENTER ESTIMATED COST OF:
BASIC EQUIPMENT $ 225,000
AIR POLLUTION CONTROL EQUIPMENT $ 90,000

FOR NEW CONSTRUCTION OR MODIFICATION, ENTER ESTIMATED START DATE: 4/05/91
ESTIMATED COMPLETION DATE: 8/1/91

FOR CHANGE OF PERMITTEE, LOCATION OR CONDITION, ENTER DATE OF OCCURRENCE:

FOR EXISTING EQUIPMENT IN OPERATION WITHOUT PRIOR PERMIT, ENTER INITIAL OPERATION DATE:

FOR THIS PROJECT, HAS A CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) DOCUMENT BEEN REQUIRED BY ANOTHER GOVERNMENTAL AGENCY? [ ] YES [X] NO

IF YES, ENTER NAME: AND SUBMIT A COPY IF APPROVED

DO YOU CLAIM CONFIDENTIALITY OF DATA? (SEE INSTRUCTIONS) [ ] YES [X] NO

I HEREBY CERTIFY, UNDER PENALTY OF PERJURY, THAT ALL INFORMATION CONTAINED HEREIN AND INFORMATION SUBMITTED WITH THIS APPLICATION ARE TRUE AND CORRECT

SIGNATURE: Charles K Stoddard

OFFICIAL TITLE OF SIGNER: Director, Facility&Maintenance

TYPE OR PRINT NAME OF SIGNER: Charles K. Stoddard

TELEPHONE NUMBER: (818 362-6822

DATE: 3/26/91

SCAQMD USE ONLY

APPLICATION NUMBER: 247254
TYPE: (B) C D
EQUIPMENT CATEGORY NUMBER: 000284 06
ASSIGNMENT UNIT 7 ENGINEER
CLASS (I) III IV
ENF. SECT.
ENGR. 4-12-91 (A) R DATE INITIAL
ENGR. A R DATE INITIAL
FEE SCHEDULE 8A 1/A $1700
VALIDATION 4/11/91 61F
CHECK OR MONEY ORDER NUMBER 16764
AMOUNT 7100

DISTRIBUTION – WHITE – ENGINEERING – CANARY – ENFORCEMENT – PINK – APPLICANT

(1 of 3)

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

PERMIT TO CONSTRUCT

9150 FLAIR DRIVE, EL MONTE, CALIFORNIA 91731

Application No. **247254**

Granted as of October 4, 1991

ID 85085

Legal Owner or Operator:

PACESETTER SYSTEMS, INC.
12884 BRADLEY AVENUE
SYLMAR, CALIFORNIA 91342
ATTN: STEPHEN R. WALTERS

Equipment Location: 15900 VALLEY VIEW COURT, SYLMAR, CA. 91341

The equipment described below and as shown on the approved plans and specifications are subject to the special condition, or conditions listed.

Equipment Description:

ETHYLENE OXIDE STERILIZATION SYSTEM NO. 1 CONSISTING OF:

1. STERILIZER NO. 1, GETINGE, MODEL NO. 8440AR1, 2' -11" W. X 4' -9" H. X 5' -0" L.

2. STEAM GENERATOR, 60 KW, WITH 201,000 BTU PER HR OUTPUT.

Conditions:

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN COMPLIANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. THIS EQUIPMENT SHALL NOT BE OPERATED UNLESS THE STERILIZER EXHAUST IS VENTED TO AN AIR POLLUTION CONTROL DEVICE WHICH IS IN FULL USE AND WHICH HAS BEEN ISSUED A PERMIT TO CONSTRUCT BY THE EXECUTIVE OFFICER.

4. NO MORE THAN 16 POUNDS OF ETHYLENE OXIDE GAS SHALL BE CHARGED TO THE STERILIZERS AT THIS FACILITY IN ANY ONE DAY.

5. NO MORE THAN 4000 POUNDS OF ETHYLENE OXIDE GAS SHALL BE USED IN THIS FACILITY IN ANY ONE CALENDER YEAR.

FILE COPY

Approval or denial of this application for permit to operate the above equipment will be made after an inspection to determine if the equipment has been constructed in accordance with the approved plans and specifications and if the equipment can be operated in compliance with all Rules of the South Coast Air Quality Management District.

Please notify S. K. TSAI 818/307-3564 when construction of equipment is complete.

This Permit to Construct is based on the plans, specifications, and data submitted as it pertains to the release of air contaminants and control measures or reduce air contaminants. No approval or opinion concerning safety and other factors in design, construction or operation of the equipment is expressed or implied.

This Permit to Construct shall serve as a temporary Permit to Operate provided the Executive Officer is given prior notice of such intent to operate.

This Permit to Construct will become invalid if the Permit to Operate is denied or if this application is cancelled. THIS PERMIT TO CONSTRUCT SHALL EXPIRE ONE YEAR FROM THE DATE OF ISSUANCE unless an extension is granted by the Executive Officer.

By Dorris M Bailey

DORRIS M. BAILEY
Principal Office Assistant

DMB/eb

FILE COPY

SCAQMD COMPUTER ASSISTED PERMIT PROCESSING (CAPPS)

FEE DATA - SUMMARY SHEET

Application No : **247254** IRS/SS No: **000-00-0000**
Previous Permit No: Previous Application No:

Company Name : **SIEMENS PACESETTER INC** Facility ID: **085085**
Equipment Street: **15900 VALLEY VIEW CT, SYLMAR, CA 91392**
Equipment Desc. : **STERILIZING EQUIPMENT**

Equipment Type : **BASIC** Fee Charged by: **B-CAT**
B-CAT NO. : **000289** C-CAT NO. : **00** Schedule: **C**
Facility Zone : **7** Deemed Compl. Date: **5/15/1991** PUBLIC NOTICE: **NO**

APPLICATION FILING FEE (PRIOR TO 7/1/90 & PLANS FEE) ..... $ **0.00**
EVALUATION FEE PRE-PAID (POST 7/1/90) ..... $ **0.00**

Evaluation Type: **PERMIT TO OPERATE (PO)** Small Business?: **NO**
Disposition : **CANCEL PO - DON'T REFUND FEE** P/O NO P/C Penalty?: **NO**
Reference App. No: Similar Permit Unit?: **NO**

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1. PERMIT PROC. FEE* (APPL FILED PRIOR TO 7/1/90) SUMMARY PERMIT FEE RATES * **$ 1,700.00** LESS FILING FEE PAID $	$	**0.00**
2. EIR	$	**0.00**
3. AIR QUALITY ANALYSIS (TABLE II FEE)	$	**0.00**
4. HEALTH RISK ASSESSMENT (TABLE II FEE)	$	**0.00**
5. SIGNIFICANT PROJECT REVIEW (TABLE II FEE)	$	**0.00**
6. SOURCE TEST REVIEW: (RULE 306(i) FEE) $1600 + [NO HRS @ $75/HR] 5/9/97	$	**0.00**
7. CEMS REVIEW (TABLE II FEE)	$	**0.00**
8. TIME AND MATERIALS (FOR PLAN APPLICATIONS ONLY) 0.00 HRS @ $ 75.00/HR	$	**0.00**
9. PERMIT PROCESSING FEE ADJUSTMENT** ADDITIONAL FEE TABLE I FEE* **$ 1,700.00** LESS EVAL. FEE PAID $ ...	$	**1,700.00**
10. OTHER FEES** (INCLUDING CANCELLATION)	$	**-1,700.00**
TOTAL:	$	**0.00**

COMMENTS: FEE WAS PAID WHEN A/N SUBMITTED. A/N IS ALREADY INACTIVATED BY CUSTOMER SERVICE. A NEW I.D. #103609 WAS ASSISGNED AND EQUIP PERMITTED UNDER A/N 298971 OR A/N 298972.

Recommended By: **GCR** DATE: **3/18/1997** REVIEWING ENG:_____ DATE:_____

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* ADJUSTED FOR SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY
** ADJUSTED FOR INCORRECT FEE SUBMITTAL, SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY

Facility ID : 85085
Name : SIEMENS PACESETTER INC
Address: 15900 VALLEY VIEW CT
SYLMAR, CA 91392-9221

Customer: C. K. STODDARD
Phone : (818)362-6822

Follow Up Transaction Number: 48637

Complaint:

Entered by: BC2773
Entered on: 10/24/94

Assigned tc: BC2773

Complaint Type: C

AN ACQUISITION AGREEMENT:
NAME IS pACESETTER, INC
A ST. JUDE MEDICAL C

Resolution:

Resolved.

South Coast Air Quality Management District

Facility Equipment List Report

Facility: 85085 SIEMENS PACESETTER INC
Last Inspection: 02/19/1993
SIC: 3845
Inspector:
Location Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221
Mailing Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221
Comment:

MR: 0601
TS: NONE
Assignment No.

Contact: C. K. STODDARD (818) 3626822
Quarter: 0001 - inspect in 4th quarter, every year
On Hold: Suspended:
Team:

Application No.	Permit No.	Permit Issue Date	Permit Status	Equipment Category		BCAT/CCAT Description	Application Date	Application Status
278881	D71408	03/19/1993	INACTIVE	000321	BCAT	TANK, SURFACE PREPARATION - OTHER ACIDS	03/02/1993	PERMIT TO OPERATE GRANTED
259031	D46563	01/14/1992	INACTIVE	44	CCAT	DRY FILTER (>100-500 SQ FT)	12/04/1991	PERMIT TO OPERATE GRANTED
259032	D46565	01/14/1992	INACTIVE	000284	BCAT	ABRASIVE BLASTING (CABINET/MACHINE/ROOM)	12/04/1991	PERMIT TO OPERATE GRANTED
258822	D46387	01/06/1992	INACTIVE	000241	BCAT	DEGREASER 111 TRICHLOROETHANE <=1lb/dVOC	12/02/1991	PERMIT TO OPERATE GRANTED
254025	D46372	01/06/1992	INACTIVE	000241	BCAT	DEGREASER 111 TRICHLOROETHANE <=1lb/dVOC	07/24/1991	PERMIT TO OPERATE GRANTED
254026	D46384	01/06/1992	INACTIVE	000241	BCAT	DEGREASER 111 TRICHLOROETHANE <=1lb/dVOC	07/24/1991	PERMIT TO OPERATE GRANTED
254027	D46311	01/02/1992	INACTIVE	000241	BCAT	DEGREASER 111 TRICHLOROETHANE <=1lb/dVOC	07/24/1991	PERMIT TO OPERATE GRANTED
254967	D45011	11/06/1991	INACTIVE	000411	BCAT	SOLDERING MACHINE	08/15/1991	PERMIT TO OPERATE GRANTED
255051	D43549	10/02/1991	INACTIVE	043901	BCAT	I C E (50-500 HP) EM ELEC GEN-DIESEL	08/16/1991	PERMIT TO OPERATE GRANTED
247254		00/00/0000		000289	BCAT	STERILIZING EQUIPMENT	04/12/1991	APPLICATION CANCELLED, REFUND ALL FEES
247255		00/00/0000		000289	BCAT	STERILIZING EQUIPMENT	04/12/1991	APPLICATION CANCELLED, REFUND ALL FEES
247256		00/00/0000		06	CCAT	AFTERBURNER, CATALYTIC	04/12/1991	APPLICATION CANCELLED, REFUND ALL FEES

New A/N's were filed under ID 103609 and Permitted.

See ID# 103609

Inspector: _____ Date: _____ Reviewed By: _____ Date: _____

South Coast Air Quality Management District

Facility Equipment List Report

Facility: 103609 PACESETTER INC, A ST JUDE MEDICAL CO
Last Inspection: 02/19/1993
SIC: 3845
Inspector:
Location Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221
Mailing Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221
Comment:

MR: 0601
TS: NONE
Assignment No.

Contact: C. K. STODDARD (818) 3626822
Quarter: 0100 - inspect in 2nd quarter, every year
On Hold: Suspended:
Team:

	Application No.	Permit No.	Permit Issue Date	Permit Status	Equipment Category		BCAT/CCAT Description	Application Date	Application Status
_____	298970	D87020	12/09/1994	ACTIVE	06	CCAT	AFTERBURNER, CATALYTIC	12/06/1994	PERMIT TO OPERATE GRANTED
_____	298971	D87021	12/09/1994	ACTIVE	000289	BCAT	STERILIZING EQUIPMENT	12/06/1994	PERMIT TO OPERATE GRANTED
_____	298972	D87022	12/09/1994	ACTIVE	000289	BCAT	STERILIZING EQUIPMENT	12/06/1994	PERMIT TO OPERATE GRANTED
_____	298965	D86964	12/07/1994	ACTIVE	000321	BCAT	TANK, SURFACE PREPARATION - OTHER ACIDS	12/06/1994	PERMIT TO OPERATE GRANTED
_____	298968	D86965	12/07/1994	ACTIVE	043901	BCAT	I C E (50-500 HP) EM ELEC GEN-DIESEL	12/06/1994	PERMIT TO OPERATE GRANTED
_____	298969	D86966	12/07/1994	INACTIVE	000411	BCAT	SOLDERING MACHINE	12/06/1994	PERMIT TO OPERATE GRANTED

Inspector: _____ Date: _____ Reviewed By: _____ Date: _____

South Coast Air Quality Management District

Engineering Division

New Source Review Regulation XIII Data Sheet

APPLICATION NUMBER : 247254
FACILITY I.D. NUMBER: 085085
FACILITY NAME : PACESETTER SYSTEMS INC
FACILITY ADDRESS : 15900 VALLEYVIEW CT
CITY : SYLMAR STATE: CA ZIP: 91342-0000

PERMIT TYPE : PC PREVIOUS APPLICATION NUMBER:
DEEMED COMPLETE: 5/15/1991

PROCESSING DECISION FOR APPLICATION:
TRANSACTION CODE: INSTALL
ENGINEER: SUSAN K TSAI

EMISSION DATA: ETHOXIDE

Max Daily (Uncontrolled) :		lbs/day
Max Daily (Controlled) :		lbs/day
Positive Balance :	0	lbs/day
30 Day Average (Controlled):		lbs/day
Annual (Controlled) :	2.088000	lbs/year

EMISSION DATA: ROG

Max Daily (Uncontrolled) :	8	lbs/day
Max Daily (Controlled) :		lbs/day
Positive Balance :	0	lbs/day
30 Day Average (Controlled):		lbs/day
Annual (Controlled) :	2.088000	lbs/year

SUPERVISOR'S APPROVAL: SUPERVISOR'S REVIEW DATE: OCT 1 '91

SCAQMD COMPUTER ASSISTED PERMIT PROCESSING (CAPPS)

FEE DATA - SUMMARY SHEET

Application No : 247254 IRS/SS No:
Previous Permit No: Previous Application No:

Company Name : PACESETTER SYSTEMS INC Facility ID: 085085
Equipment Street: 15900 VALLEYVIEW CT, SYLMAR, CA 91342
Equipment Desc. : STERILIZING EQUIPMENT 10/01
B-CAT NO. : 000289 C-CAT NO. : 00 Schedule: C PUBLIC NOTICE REQUIRED: NO

APPLICATION FILING FEE (PRIOR TO 7/1/90 & PLANS FEE) ..... $
EVALUATION FEE PRE-PAID (POST 7/1/90) ..... $ 1,700.00
Evaluation Type: PERMIT TO CONSTRUCT (PC) Small Business?: NO
Disposition: APPROVE PC P/O NO P/C Penalty?: NO
Reference App. No: Identical Permit Unit?: NO

1. PERMIT PROC. FEE* (APPL FILED PRIOR TO 7/1/90)	1.	$	0.00
2. EIR	2.	$	0.00
3. AIR QUALITY ANALYSIS	3.	$	0.00
4. HEALTH RISK ASSESSMENT	4.	$	0.00
5. SIGNIFICANT PROJECT REVIEW	5.	$	0.00
6. SOURCE TEST REVIEW	6.	$	0.00
7. CEMS REVIEW	7.	$	0.00
8. TIME AND MATERIALS (FOR PLAN APPLICATIONS ONLY)	8.	$	0.00
9. PERMIT PROCESSING FEE ADJUSTMENT** ADDITIONAL FEE	9.	$	0.00
10. OTHER FEES** (INCLUDING CANCELLATION)	10.	$	0.00
TOTAL:		$	0.00

PROCESSED
OCT 04 1991
DATA ENTRY UNIT
By

COMMENTS: FOR PERMIT WORDING AND CONDITIONS SEE PAGE 1 & 2 OF PROCESSING SHEETS.

Recommended By: SKT DATE: 9/30/1991 REVIEWING ENG: DATE: OCT 1 '91

* ADJUSTED FOR SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY

** ADJUSTED FOR INCORRECT FEE SUBMITTAL, SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY

SCAQMD COMPUTER ASSISTED PERMIT PROCESSING (CAPPS)

AEIS DATA SHEET

(For P/C Only)

Company Name **PACESETTER SYSTEMS INC** Facility ID **085085**

Equipment Address **15900 VALLEYVIEW CT, SYLMAR CA 91342**

APPLICATION NUMBER	**247254**
ESTIMATED COMPLETION DATE	**12/01/1991**
EQUIPMENT B-CAT	**000289**
EQUIPMENT C-CAT	**00**
EQUIPMENT DESCRIPTION	**STERILIZING EQUIPMENT**
EQUIPMENT TYPE	**B**
SCHEDULE/STEP	**3/C**

Engineers Name: **SUSAN K TSAI** Date: **9/30/1991**

Supervisor's Name: _____ Review Date: OCT 1 '91

FORM CAPPS-200B

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT	PAGES 7	PAGE 1
ENGINEERING DIVISION	APPL. NO. 247254-6	DATE 9-25-91
APPLICATION PROCESSING AND CALCULATIONS	PROCESSED BY AQC	CHECKED BY SKT

PACESETTER SYSTEMS, INC.
12884 BRADLEY AVENUE
SYLMAR, CA 91342

EQUIPMENT LOCATION:

15900 VALLEY VIEW COURT, SYLMAR, CA 91342

EQUIPMENT DESCRIPTIONS:

APPLICATION NO. 247254

ETHYLENE OXIDE STERILIZATION SYSTEM NO. 1 CONSISTING OF :

1. STERILIZER NO. 1, GETINGE, MODEL NO. 8440AR1, 2'-11" W. X 4'-9" H. X 5'-0" L.

2. STEAM GENERATOR, 60 KW, WITH 201,000 BTU PER HR OUTPUT.

APPLICATION NO. 247255

ETHYLENE OXIDE STERILIZATION SYSTEM NO. 2 CONSISTING OF :

1. STERILIZER NO. 2, GETINGE, MODEL NO. 8430AR1, 2'-2" W. X 3'-0" H. X 5'-0" L.

2. STEAM GENERATOR, 60 KW, WITH 201,000 BTU PER HR OUTPUT.

APPLICATION NO. 247256

AIR POLLUTION CONTROL SYSTEM CONSISTING OF :

1. CATALYTIC OXIDIZER/ABATOR, DONALDSON, 7' W. X 5' H. X 21' L., WITH A 80 KW PREHEATER, A HEAT EXCHANGER, A PREFILTER, AND FOUR DCI SURE-SORBER CATALYTIC FILTERS.

2. EXHAUST SYSTEM WITH A 1000 SCFM CENTRIFUGAL AIR BLOWER VENTING TWO ETHYLENE OXIDE STERILIZING SYSTEMS.

CONDITIONS

APPLICATIONS NO. 247254 & 247255

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THIS APPLICATION UNDER WHICH A PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. THIS EQUIPMENT SHALL NOT BE OPERATED UNLESS THE STERILIZER EXHAUST IS VENTED TO AN AIR POLLUTION CONTROL DEVICE WHICH IS IN FULL USE AND WHICH HAS BEEN ISSUED AN PERMIT TO CONSTRUCT BY THE EXECUTIVE OFFICER.

4. NO MORE THAN 16 POUNDS OF ETHYLENE OXIDE GAS SHALL BE CHARGED TO THE STERILIZERS AT THIS FACILITY IN ANY ONE DAY.

5. NO MORE THAN 4000 POUNDS OF ETHYLENE OXIDE GAS SHALL BE USED IN THIS FACILITY IN ANY ONE CALENDER YEAR.

APPLICATION NO. 247256

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THIS APPLICATION UNDER WHICH A PERMIT IS ISSUED UNLESS OTHERWISE NOTED.

2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.

3. ONLY ONE STERILIZER MAY VENT ITS PRIMARY ETHYLENE OXIDE EXHAUST TO THE CATALYTIC OXIDIZER/ABATOR AT ANY ONE TIME.

4. THE TEMPERATURE OF THE EXHAUST FROM THE CATALYST BED SHALL BE MAINTAINED BETWEEN 300^{O}F AND 500^{O}F AS INDICATED BY A PROPER TEMPERATURE GAGE.

5. RECORDS SHALL BE MAINTAINED TO PROVE COMPLIANCE WITH CONDITION NO. 4. THE RECORDS SHALL BE MADE AVAILABLE TO THE DISTRICT UPON REQUEST.

BACKGROUND

Pacesetter Systems, Inc. manufactures heart pacemakers and their facility is presently located at 12884 Bradley Avenue in Sylmar, CA. Their operations will be completely moved to another facility at 15900 Valley View Court in Sylmar, CA. Pacesetter plans to purchase two new sterilizers and abator system (catalytic oxidizer) to conduct their sterilization operations in this new facility.

These new sterilizers will be constructed in a fire-proof sterilization room at the Valley View facility, and utilize 100% ethylene oxide (EtO) to sterilize components of the pacemakers, pacers and leads. The abator system will control all EtO emissions from the operation of the sterilizers, and has an expected efficiency of 99.9%. Complete aeration of the product loads will be conducted inside the sterilizers, so any EtO residue left upon completion of sterilization will be vented to the abator. The room in which the sterilizers are situated will be continuously vented to the abator as well to control any fugitive EtO.

A typical load of product will contain equal quantities of pacers and leads. Pacers are constructed of a Titanium can with an epoxy connector top. Leads are made of silicone tubing over a metal conductor with a connector that fits into the pacer connector on one end and a metal electrode on the other. Each pacer or lead is packaged in two 0.025" thick, vacuum formed XT Polymer trays; the inner tray measures 4.25" x 7.25", and the outer one is 5" x 8". The 32 cubic foot sterilizer will typically hold 400 packages, and the 69 cubic foot unit will hold 1400 packages.

Ethylene oxide is a carcinogenic air contaminant. Permitting and operation of the sterilizers are subject to the requirements of Rules 1401 and 1405, respectively.

Applications for Permits to Construct the sterilizers and abator system were submitted on April 10, 1991.

PROCESS DESCRIPTION

The sterilizers use 100% ethylene oxide (EtO) to sterilize components of heart pacemakers: pacers and leads. The total EtO usage is projected to be 5.65 pounds per day for both sterilizers.

Batch loads of pacers and leads are placed in the sterilizers, and experience a 22 hour sterilization cycle. The sequence of operation of the sterilization cycles is as follows:

a. The load is heated by recirculating the chamber air for a pre-set time period of approximately 20 minutes.

b. The chamber is evacuated by the vacuum pump at a pre-set rate until a pre-set vacuum level is achieved.

c. The chamber is held under vacuum for 10 minutes to determine if any leaks exist.

d. Compressed nitrogen gas is admitted to the chamber at a pre-set pressure. Chamber is re-evacuated, and charged again with nitrogen gas for a pre-set number of pulses.

e. The load is humidified with pulse injections of steam to a pre-set absolute pressure level.

f. The load is held at temperature and humidity for a pre-selected pre-conditioning time.

g. Ethylene oxide (EtO) gas is admitted to the chamber at a pre-set rate until a pre-set pressure is achieved. Nitrogen gas is admitted to chamber at a pre-set rate until a pre-set pressure is achieved. A subsequent charge of nitrogen gas into chamber purges gas lines of EtO.

h. Chamber pressure is maintained for the pre-selected sterilizing time period.

i. Primary exhaust of the chamber gases commences through the ventilation system at a pre-set rate to an abator (a catalytic control device) where 99.9% of EtO in the primary chamber exhaust is oxidized to carbon dioxide and water.

j. Chamber is evacuated to pre-set vacuum level. Nitrogen gas is admitted to chamber at a pre-set rate until pre-set pressure is attained (Steps i & j are repeated at least 2 additional times).

k. Complete chamber aeration commences by alternating a pre-set number of vacuum and air purges.

l. Air is admitted to the chamber through the bacterial retentive air filter until ambient atmospheric pressure is achieved.

The sterilization chamber is heated by recirculating water through a jacket lining the ceiling, walls, and floor. The water is heated by steam provided by a 60 KW electric steam generator. A centrifugal-type fan is fitted to the roof of the chamber to circulate internal air and gases, and powered by an external electric motor. All chamber air and gases are exhausted through a ventilation system ducted to the ethylene oxide abator system.

In the abator system, the ethylene oxide contaminated air is passed through 4 catalytic filters containing a catalyst made up of a manganese dioxide and copper oxide mixture. The ethylene oxide adsorbs to the catalyst, and is oxidized to carbon dioxide and water according to the following equation:

$$2C_2H_4O + 5O_2 \text{ ----------> } 4CO_2 + 4H_2O + \text{heat}$$

Prior to introducing EtO to the abator system, there is a preheat cycle of approximately 45 minutes to bring the system to an operating temperature of 300 degrees Fahrenheit (after initial start up, the abator will operate continuously). The fan motor and heater are energized and the dampers are positioned in the preheat mode. The warm air heats up the catalytic beds. When the sensor on the catalytic beds senses a temperature of 300 degrees Fahrenheit, the system will end the preheat cycle and open the EtO feed valve. Due to the release of heat during the oxidation of ethylene oxide, the heater is used very little once the catalytic beds have reached the operating temperature.

Air from the sterilizer chambers and sterilization room are pulled into the abator system by a 1000 scfm centrifugal fan. Any particulate in the incoming air is removed by the Dustfoe prefilters. The air then passes through a recuperative heat exchanger, heating coils, and then into the catalytic beds. The EtO free air proceeds through the fans, and a portion of the discharge is recirculated to the hot side of the recuperative heat exchanger to preheat incoming air. The amount of flow directed to the heat exchanger is controlled depending upon the temperature of the catalytic beds. In addition, a temperature control switch will close the EtO feed valve should the catalytic bed temperature rise above 550 degrees Fahrenheit.

Safety mechanisms are provided to restrict the EtO feed valve from opening unless the following criteria are satisfied:

1. Catalytic bed temperature at a minimum of 300 degrees Fahrenheit
2. Catalytic bed temperature below 550 degrees Fahrenheit
3. Minimum air flow rate of 900 cfm
4. Safety blow-out pan properly sealed

EMISSION AND RISK CALCULATIONS

Ethylene Oxide Emission Calculations:

Operating Schedule: 8 hrs/day, 5 days/week, 52 weeks/yr
Maximum Amount of EtO usage: 16 lb/day

R1 = uncontrolled emissions = 16 lbs/day

R2 = controlled emissions = 16 lbs/day x (1 - 0.999)
= 0.016 lbs/day

Yearly average emission = 0.016 lbs/day X (261/365)
= 0.011 lb/day

Risk Assessment Calculation:

$$MICR = Q \times (X/Q) \times U \times MP$$

MICR - Maximum Individual Cancer Risk
Q - Emission Rate of EtO in lb/day
X/Q - EtO Concentration (Tables 3 & 4, Rule 1401)
U - Unit Risk Factor for EtO (Table 1, Rule 1401)
MP - Multiple Pathway Adjustment Factor

Risk at the Nearest Residential Area:

Q = 0.011 lb/day
X/Q = 0.673 [ug/m3] / [lb/day]
U = 0.000088 [1/(ug/m3)]
MP = 1

MICR = 0.011 x 0.673 x 0.000088 x 1
= 0.65×10^{-6}

Risk at the Commercial/Industrial Locations:

Q = 0.011 lb/day
X/Q = 3.01 [ug/m3] / [lb/day]
U = 0.000088 [1/(ug/m3)]
MP = 1

MICR = 0.011 x 3.01 x 0.000088 x 1
= 2.9×10^{-6}

Multiplication factor for adjustment for land use considerations at commercial/industrial locations is 0.15.

Adjusted Risk = $2.9 \times 10^{-6} \times 0.15 = 0.44 \times 10^{-6}$

The off-site commercial/industrial risk times 0.15 is less than one-in-one million and the nearest residential area risk is also less than one-in-one million, therefore, the facility is considered to have passed the screening assessment.

RULE EVALUATION

Rule 212 Compliance with this rule is expected.

The maximum individual cancer risk is less than one-in-one million.

Rule 401 No visible emissions expected.

Rule 402 No nuisance expected.

Reg. XIII Compliance with this regulation is expected.

The air pollution control system satisfied the BACT requirement.

Rule 1401 The maximum individual cancer risk (MICR) is less than one-one in million, compliance with this rule is expected.

Rule 1405 Compliance with this rule is expected.

All exhaust of EtO must be vented an control device with 99.6% efficiency. The abator system is expected to achieve 99.9% efficiency.

RECOMMENDATIONS

Based on the above evaluation, conditional Permits to Construct are recommended for Applications No. 247254, 247255, and 247256.

RISK APPLICATION TRACKING FORM

COMPANY NAME: PACESETTER SYSTEMS INC.

FACILITY LOCATION: 15900 VALLEYVIEW CT, SYLMAR, CA 91342

FACILITY I.D. NO.: 85085

EQUIPMENT LOCATION WITHIN FACILITY: WEST SIDE OF BUILDING, 260FT FROM ROXFORD STREET PROERTY LINE

EQUIPMENT DESCRIPTION: ETHYLENE OXIDE STERILIZER #1, GETINGE, MODEL NO 8440 AR/

APPLICATION NO.: 247254

RELATED APPLICATION NOS.: 247256

CARCINOGENIC EMISSIONS EVALUATED: (attach additional sheets as necessary)

COMPOUNDS EMITTED		EMISSION RATE (#/YR)	CONTROL EQUIPMENT	C-CAT NO.	CONTROL EFFICIENCY
ETHYLENE OXIDE	1401 [✓] 212 [ ]	2.088	CATALYTIC OXIDIZER/ABATOR	16	99.9%
	1401 [ ] 212 [ ]				
	1401 [ ] 212 [ ]				
	1401 [ ] 212 [ ]				

TYPE OF ANALYSIS PERFORMED: SCREENING [✓] DETAILED MODELING [ ] BOTH [ ] NONE [ ]

T-BACT REQUIRED YES [✓] NO [ ] | 212 P/U RISK: | 1401 P/U RISK: 0.3340^{-6} | 1401 CUM RISK:

CANCER BURDEN CALCULATED NO [✓] YES [ ] IF YES CANCER BURDEN _____

CEQA PROCESS REQUIRED YES [ ] NO [✓] | PERMIT CONDITIONED TO EXPIRE ON JUNE 1, 1995 YES [ ] NO [ ]

EXEMPTION APPLIED NO [✓] YES [ ] IF YES, SECTION APPLIED: 1401(g)( )( )

PERMIT ISSUED YES [✓] NO [ ] | RESOLUTION DATE:

COMMENT / REASON FOR DENIAL:

PROCESS ENGINEER NAME: Susan K Tsai | DATE 9/30/91

APPROVED BY | DATE OCT 1 '91

ENGINEERING DIVISION····MEMORANDUM

TO	FROM	DATE
FILE	SKT	9-26-91
REFERENCE (Facesetter) AQC		PERMIT APPL. NO.

SUBJECT

T/C Steve Walters

- Informed him that the grade of the location of the facility can not be considered when performing the screening analysis.

- Since the facility is in an industrial location adjustment for Land Use consideration can be applied.

- The maximum allowable ETO per day is 1666/day.

- Condition will include daily and yearly ETO use limits.

- Will call back after checking with clients.

9-26-91

T/C Steve Walters

- Have confirmed with client that 1666/day of ETO use limit is achievable.

16-50D115-R1

AQC inc

AN ENVIRONMENTAL ENGINEERING CONSULTING FIRM

September 18, 1991

Susan Tsai
South Coast AQMD
9150 Flair Drive
El Monte, CA 91731

Re: Sterilizer and Abator System Permit Application
#247254, 247255, and 247256 for:
Pacesetter Systems, Inc.
15900 Valley View Court
Sylmar, CA 91342

Dear Susan:

Per our discussion, we have re-evaluated the initial MICR calculations submitted with the Engineering Evaluations on 20 August 1991 for the above permit applications. Our evaluation took into account the provisions for dispersion factors outlined in the Air Toxic Rules Risk Assessment Guidelines.

Subsequently, we have attached a revised MICR screening which has taken into consideration the horizontal distance from the EtO Abator to the nearest residential receptor. In addition, the stack height parameter was revised taking into account the grade from the property fenceline to ground level of this residential receptor. We have attached maps which will serve as support documentation for our calculations.

The MICR screening revealed the risk to the nearest residential receptor will not exceed one in one million for ethylene oxide usages up to 31 pounds per day. Please revise the Engineering Evaluations to allow for this usage as a facility limit. It is recommended the sterilizers' permit condition #6 read as the following: "The total quantity of ethylene oxide gas used in the sterilization equipment at this facility shall not exceed 31 pounds on any one day."

In light of the approaching move-in date, we appreciate any expeditious action taken to issue the Permits to Construct. If there are any questions, please do not hesitate to call.

Sincerely,

Steven R. Walters

Steve Walters
Project Engineer

cc: G. Rhett, SCAQMD
C. Stoddard, Pacesetter Systems

3230 FALLOW FIELD DRIVE
SUITE 200, DIAMOND BAR
CA 91765-3479
TEL (714) 468 - 1700
FAX (714) 468 - 1704

Attachment 1

Maximum Individual Cancer Risk Calculations

The nearest residential receptor is located at 15906 Roxford Street. The horizontal distance from the EtO Abator System to this receptor is 420 ft +/- 20 ft. The stack height, the vertical distance from the EtO Abator System to ground level of this receptor, is 59 ft +/- 5 ft. This value takes into account the building height (39 ft) and the grade of the grassy hill which separates the property fenceline and Roxford Street (20 ft +/- 5 ft). This stack height parameter does not exceed the limit of 2.5 times the height of the nearest building (which is approximately equal in height to the Pacesetter building).

MICR Screening:

Eqn (1) $MICR = Q \times (X/Q) \times U \times MP$

MICR - Maximum Individual Cancer Risk
Q - Emission Rate of EtO in lb/day
X/Q - EtO Concentration (Tables 3 & 4, Rule 1401)
U - Unit Risk Factor for EtO (Table 1, Rule 1401)
MP - Multiple Pathway Adjustment Factor

Calculations-

MICR = 9.9×10^{-7} (less than one in one million)

X/Q = 0.358 [ug/m3] / [lb/day]

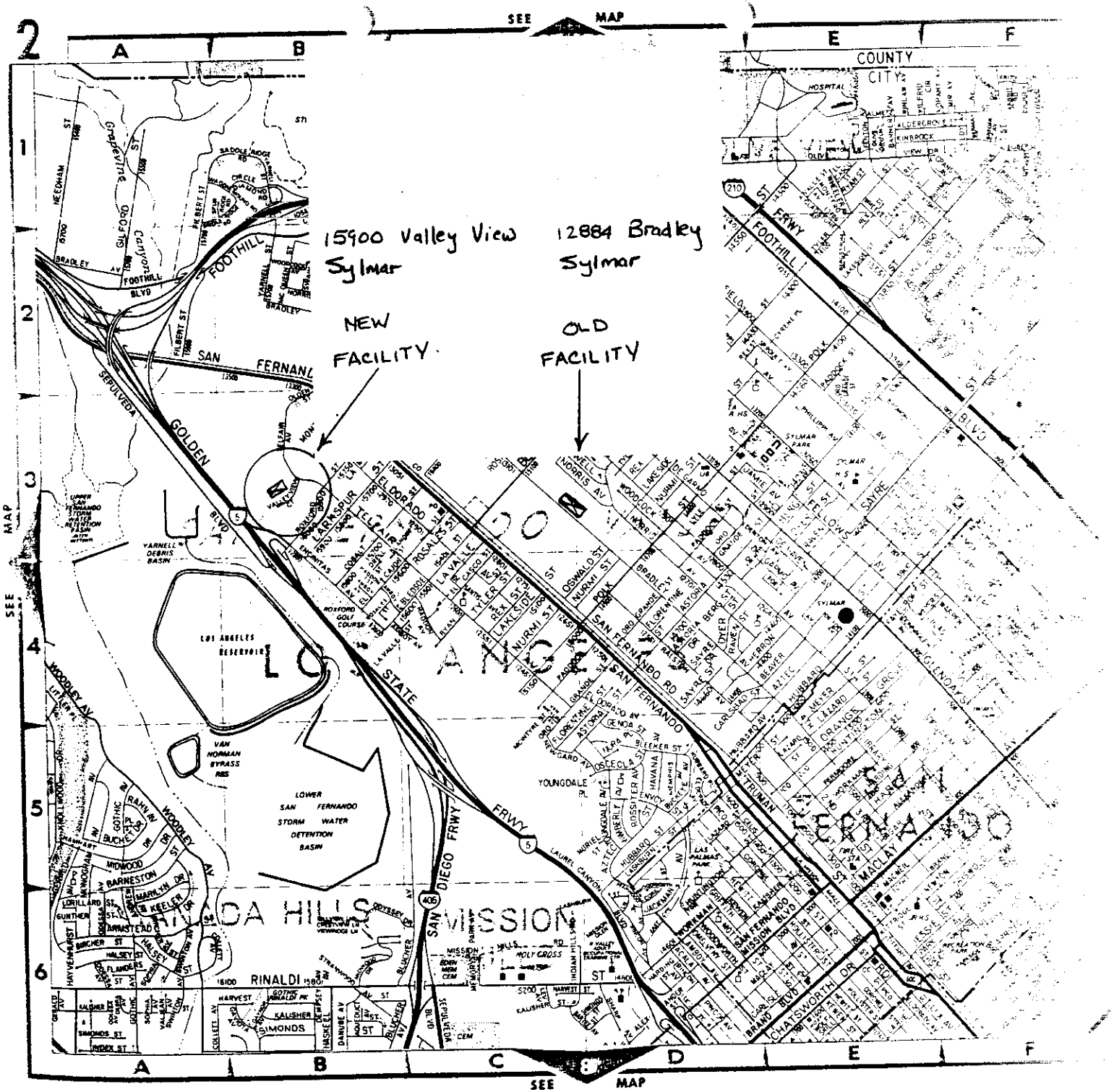
U = 0.000088 [1/(ug/m3)]

MP = 1

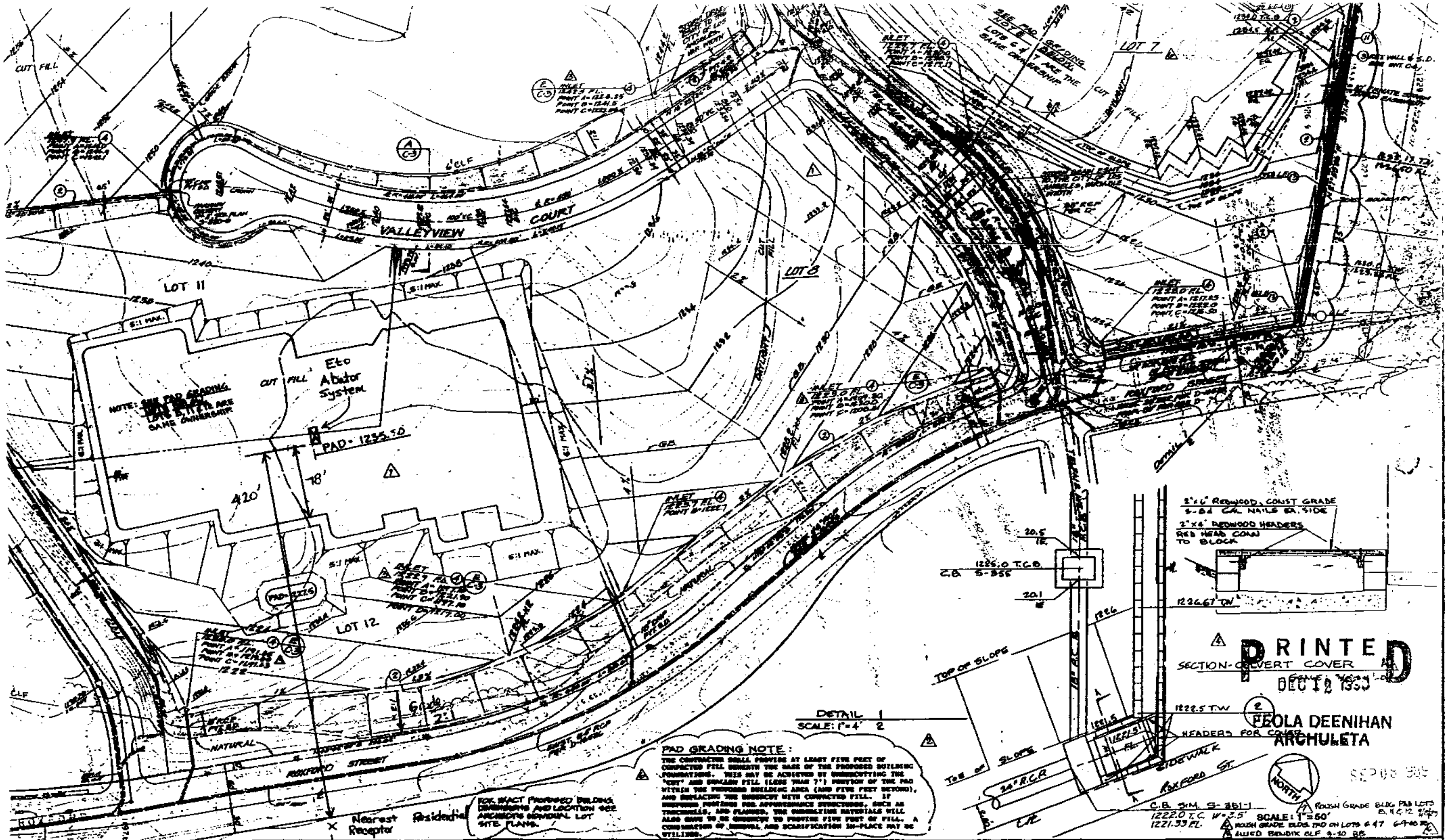
$9.9 \times 10^{-7} = Q \times 0.358 \times 0.000088 \times 1$

Q = 0.0314 lbs/day (emissions after control)

Usage = 31.4 lbs/day



COPYRIGHT © 1987 BY Thomas Bros. Maps



PSOMAS & ASSOCIATES

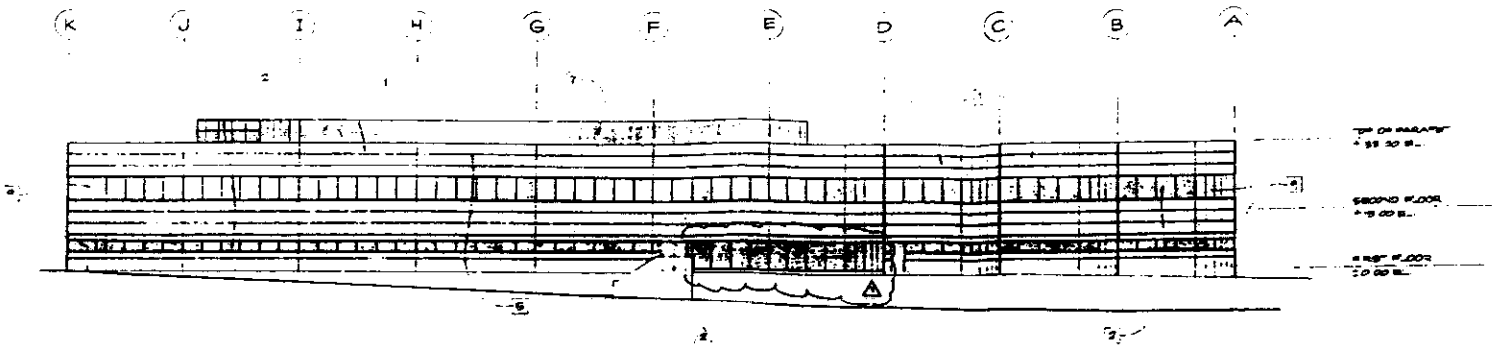
CIVIL ENGINEERS / LAND PLANNERS / LAND SURVEYORS
3187 REDHILL AVE., STE. 250
COSTA MESA, CA 92626
PHONE 714 • 751-7373

OWNER/DEVELOPER
THOMPSON PROPERTIES, INC.

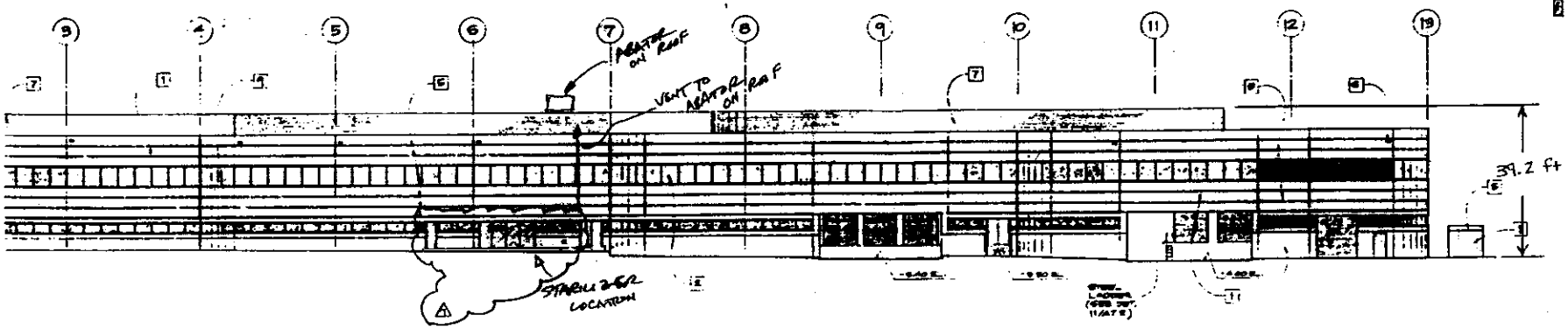
TRACT NO. 44622
ROUGH GRADING PLAN
SYLMAR, CALIFORNIA

DATE 4-28-87
SCALE 1"=100'

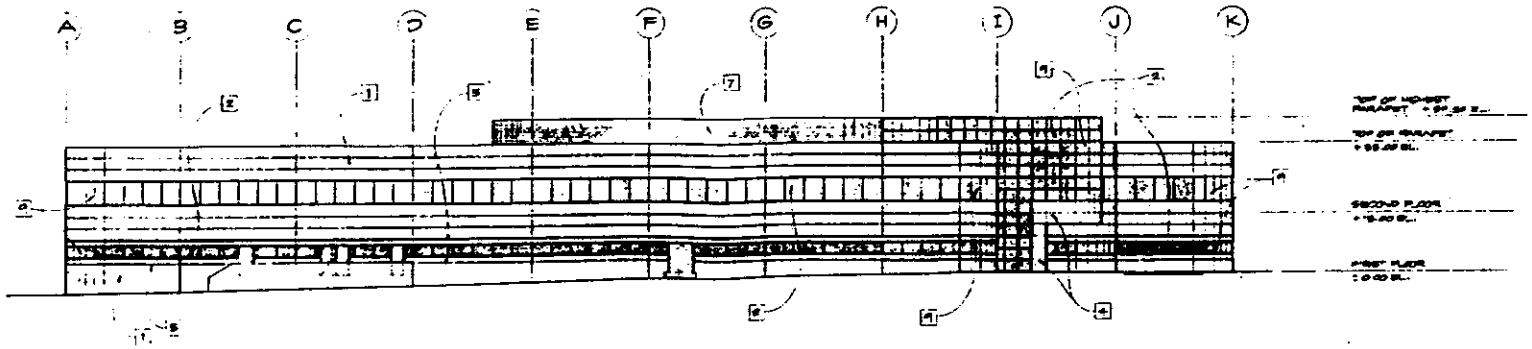
C-2



WEST ELEVATION



SOUTH ELEVATION



EAST ELEVATION

1-6-89 BULLETIN #2
1-16-90 BULLETIN #6

PRINTED
DEC 12 1990

FEOLA DEENIHAN ARCHULETA

Pacesetter Systems, Inc.
Sylmar, California

ELEVATIONS

A 3.1

ENGINEERING DIVISION····MEMORANDUM

TO	FROM	DATE
FILE	SKT	8-22-91
REFERENCE: AQC.		PERMIT APPL. NO.

SUBJECT: Processor Systems, Inc. ETC.

T/C Steve Walters.

The risk of 1.4×10^{-6} is too high, modeling is required.

Gave him a copy of risk assessment package, wait for his decision.

16-50D115-R1

AQC inc

AN ENVIRONMENTAL ENGINEERING CONSULTING FIRM

August 19, 1991

George Rhett
South Coast AQMD
9150 Flair Drive
El Monte, CA 91731

Re: Sterilizer and Abator System Permit Application
#247254, 247255, and 247256 for:
Pacesetter Systems, Inc.
15900 Valley View Court
Sylmar, CA 91342

Dear Mr. Rhett:

Attached is the completed preliminary engineering evaluation for the sterilizers and abator system permit applications for Pacesetter Systems. Per your request, we have provided the report on your computer disk as well. We hope this will help expedite your review of these applications.

If there are any questions, please do not hesitate to call.

Sincerely,

Steven R. Walters

Steve Walters
Project Engineer

cc: Chuck Stoddard, Pacesetter Systems
Terry Williams, Pacesetter Systems

3230 FALLOW FIELD DRIVE
SUITE 200, DIAMOND BAR
CA 91765-3479
TEL (714) 468 - 1700
FAX (714) 468 - 1704

CONTENTS

1.0 FACILITY AND EQUIPMENT INFORMATION

Applicant: **Pacesetter Systems, Inc.**

Mailing Address: 12884 Bradley Avenue
Sylmar, CA 91342

Equipment Address: 15900 Valley View Court
Sylmar, CA 91342

Equipment Descriptions:

Application #247254

Ethylene Oxide gas sterilizing system consisting of :

1. Sterilizer, Getinge, Model 8440AR1, with internal chamber dimensions of 35" W x 57" H x 60" L
2. 60 KW electric steam generator with 201,000 Btu/hr output

Application #247255

Ethylene Oxide gas sterilizing system consisting of :

1. Sterilizer, Getinge, Model 8430AR1, with internal chamber dimensions of 26" W x 36" H x 60" L
2. 60 KW electric steam generator with 201,000 Btu/hr output

Application #247256

Air Pollution Control System consisting of :

1. Catalytic Oxidizer - Abator System; Donaldson Company, external dimensions of 7' W x 5' H x 21' L, 80 KW preheater, 1000 scfm centrifugal air blower, and 4 DCI Sure-Sorber catalytic filters with outer dimensions of 24" W x 24" H x 12" L each.

2.0 BACKGROUND

Pacesetter Systems, Inc. manufactures heart pacemakers and their facility is presently located at 12884 Bradley Avenue in Sylmar, CA. Their operations will be completely moved to another facility at 15900 Valley View Court in Sylmar, CA. Pacesetter plans to purchase two new sterilizers and abator system (catalytic oxidizer) to conduct their sterilization operations in this new facility.

These new sterilizers will be constructed in a fire-proof sterilization room at the Valley View facility, and utilize 100% ethylene oxide (EtO) to sterilize components of the pacemakers, pacers and leads. The abator system will control all EtO emissions from the operation of the sterilizers, and has a manufactured efficiency of 99.9%. Complete aeration of the product loads will be conducted inside the sterilizers, so any EtO residue left upon completion of sterilization will be vented to the abator. The room in which the sterilizers are situated will be continuously vented to the abator as well to control any fugitive EtO.

A typical load of product will contain equal quantities of pacers and leads. Pacers are constructed of a Titanium can with an epoxy connector top. Leads are made of silicone tubing over a metal conductor with a connector that fits into the pacer connector on one end and a metal electrode on the other. Each pacer or lead is packaged in two 0.025" thick, vacuum formed XT Polymer trays; the inner tray measures 4.25" x 7.25", and the outer one is 5" x 8". The 32 cubic foot sterilizer will typically hold 400 packages, and the 69 cubic foot unit will hold 1400 packages.

Ethylene oxide is a carcinogenic air contaminant. Permitting and operation of the sterilizers are subject to the requirements of Rules 1401 and 1405, respectively.

Applications for permits to construct/operate the sterilizers and abator system were submitted on April 10, 1991.

3.0 PROCESS DESCRIPTION

The sterilizers use 100% ethylene oxide (EtO) to sterilize components of heart pacemakers: pacers and leads. The total EtO usage is projected to be 5.65 pounds per day for both sterilizers.

Batch loads of pacers and leads are placed in the sterilizers, and experience a 22 hour sterilization cycle. The sequence of operation of the sterilization cycles is as follows:

a. The load is heated by recirculating the chamber air for a pre-set time period of approximately 20 minutes.

b. The chamber is evacuated by the vacuum pump at a pre-set rate until a pre-set vacuum level is achieved.

c. The chamber is held under vacuum for 10 minutes to determine if any leaks exist.

d. Compressed nitrogen gas is admitted to the chamber at a pre-set pressure. Chamber is re-evacuated, and charged again with nitrogen gas for a pre-set number of pulses.

e. The load is humidified with pulse injections of steam to a pre-set absolute pressure level.

f. The load is held at temperature and humidity for a pre-selected pre-conditioning time.

g. Ethylene oxide (EtO) gas is admitted to the chamber at a pre-set rate until a pre-set pressure is achieved. Nitrogen gas is admitted to chamber at a pre-set rate until a pre-set pressure is achieved. A subsequent charge of nitrogen gas into chamber purges gas lines of EtO.

h. Chamber pressure is maintained for the pre-selected sterilizing time period.

i. Primary exhaust of the chamber gases commences through the ventilation system at a pre-set rate to an abator (a catalytic control device) where 99.9% of EtO in the primary chamber exhaust is oxidized to carbon dioxide and water.

j. Chamber is evacuated to pre-set vacuum level. Nitrogen gas is admitted to chamber at a pre-set rate until pre-set pressure is attained (Steps i & j are repeated at least 2 additional times).

k. Complete chamber aeration commences by alternating a pre-set number of vacuum and air purges.

1. Air is admitted to the chamber through the bacterial retentive air filter until ambient atmospheric pressure is achieved.

The sterilization chamber is heated by recirculating water through a jacket lining the ceiling, walls, and floor. The water is heated by steam which is provided by a 60 KW electric steam generator with 201,000 Btu/hr output. A centrifugal-type fan is fitted to the roof of the chamber to circulate internal air and gases, and powered by an external electric motor. All chamber air and gases are exhausted through a ventilation system ducted to the ethylene oxide abator system.

In the abator system, the ethylene oxide contaminated air is passed through 4 catalytic filters containing a catalyst made up of a manganese dioxide and copper oxide mixture. The ethylene oxide adsorbs to the catalyst, and is oxidized to carbon dioxide and water according to the following equation:

$$2C_2H_4O + 5O_2 \text{ ----------> } 4CO_2 + 4H_2O + \text{heat}$$

Prior to introducing EtO to the abator system, there is a preheat cycle of approximately 45 minutes to bring the system to an operating temperature of 300 degrees Fahrenheit (after initial start up, the abator will operate continuously). The fan motor and heater are energized and the dampers are positioned in the preheat mode. The warm air heats up the catalytic beds. When the sensor on the catalytic beds senses a temperature of 300 degrees Fahrenheit, the system will end the preheat cycle and open the EtO feed valve. Due to the release of heat during the oxidation of ethylene oxide, the heater is used very little once the catalytic beds have reached the operating temperature.

Air from the sterilizer chambers and sterilization room are pulled into the abator system by a 1000 scfm centrifugal fan. Any particulate in the incoming air is removed by the Dustfoe prefilters. The air then passes through a recuperative heat exchanger, heating coils, and then into the catalytic beds. The EtO free air proceeds through the fans, and a portion of the discharge is recirculated to the hot side of the recuperative heat exchanger to preheat incoming air. The amount of flow directed to the heat exchanger is controlled depending upon the temperature of the catalytic beds. In addition, a temperature control switch will

close the EtO feed valve should the catalytic bed temperature rise above 550 degrees Fahrenheit.

Safety mechanisms are provided to restrict the EtO feed valve from opening unless the following criteria are satisfied:

1. Catalytic bed temperature at a minimum of 300 degrees Fahrenheit
2. Catalytic bed temperature below 550 degrees Fahrenheit
3. Minimum air flow rate of 900 cfm
4. Safety blow-out pan properly sealed

4.0 EMISSION AND RISK CALCULATIONS

Ethylene Oxide Emission Calculations:

Projected Usage = 1,475 lbs/yr

R1 = uncontrolled emissions
= 5.65 lbs/day (based upon 261 days per year)

R2 = controlled emissions
= 5.65 lbs/day (1 - 0.999)
= 5.65×10^{-3} lbs/day

MICR Screening:

Eqn (1) $MICR = Q \times (X/Q) \times U \times MP$

MICR - Maximum Individual Cancer Risk
Q - Emission Rate of EtO in lb/day
X/Q - EtO Concentration (Tables 3 & 4, Rule 1401)
U - Unit Risk Factor for EtO (Table 1, Rule 1401)
MP - Multiple Pathway Adjustment Factor

Calculations-

Q = EtO Usage x (1-abator efficiency)
= 1475 lb/year x 0.1%
= 1.475 lb/year x (1 year/261 days)
= 0.00565 lb/day of EtO emission

X/Q = 3.01 [ug/m3] / [lb/day]

U = 0.000088 [1/(ug/m3)]

MP = 1

MICR = $0.00565 \times 3.01 \times 0.000088 \times 1$
= 1.4×10^{-6}
= 1 in One Million

5.0 RULE EVALUATION

Rule 401. No visible emissions expected.

Rule 402 No nuisance expected.

Rule 1401 Since ethylene oxide is considered a carcinogenic air contaminant, the permitting of the sterilizers is subject to District Rule 1401. The abator system will be considered T-BACT for control of the ethylene oxide emissions from the sterilizers. In order for the Executive Officer to accept the construction of these sterilizers, the maximum individual cancer risk (MICR) resulting from the ethylene oxide emissions can not exceed ten in one million (1×10^{-5}) at any receptor location. The MICR was estimated to be one in one million.

Rule 1405 Per Section d (2), for ethylene oxide usages of more than 400 and less than or equal to 4,000 pounds per calendar year, all exhaust of EtO must be vented an control device with 99.9% efficiency. The abator system is expected to achieve 99.9% efficiency. Provisions of Section d(4) will be met in advance since the sterilizers will utilize 100% ethylene oxide.

Leak tests shall be conducted every six months as specified in paragraph (f), Test Methods. Additionally, records shall be maintained on the results of leak tests, and either the number of sterilizer cycles and the pounds of ethylene oxide used per cycle for each sterilizer each day; or the total pounds of ethylene oxide purchased and used per calendar year, provided that monthly totals are also kept.

Reg XIII The abator system will be considered T-BACT for the sterilizers. The modeling requirement per Rule 1303 for the new facility will not apply since modeling for ROG is currently not required. Additionally, per Rule 1304, offset emissions will not be required given the relocation to the new facility is expected to result in an overall net emission decrease of ROG, and that BACT is applied.

6.0 RECOMMENDATIONS

Sterilizers

Issuance of permits to construct the sterilizers is recommended with the following conditions:

1. Operation of this equipment shall be conducted in accordance with all data and specifications submitted with this application under which a permit is issued unless otherwise noted.

2. This equipment shall be properly maintained and kept in good operating condition at all times.

3. Only one sterilizer may vent its primary ~~chamber exhaust~~ to the abator system at a time.

4. This equipment must not be operated unless the sterilizer exhaust is vented to an air pollution control device which is in full use and has been issued an permit to construct and/or permit to operate by the Executive Officer.

5. This equipment shall operate in accordance with the requirements of Rule 1405.

6. During the safety qualification trials of the sterilizers, the total quantity of sterilant gas used in this equipment shall not exceed 12 pounds on any one day. Upon completion of the qualification trials, the total quantity of sterilant gas used in this equipment shall not exceed 6 pounds on any one day.

7. The operator shall keep adequate records to verify daily usage of sterilant gas, daily sterilizer cycles, and results of leak tests in a manner approved by the Director of Enforcement in writing. Such records shall be retained at the facility for a period of two years and be made available upon request of the Executive Officer or his representative.

Abator System

Issuance of permits to construct the abator system is recommended with the following conditions:

1. Operation of this equipment shall be conducted in accordance with all data and specifications submitted with this application under which a permit is issued unless otherwise noted.

2. This equipment shall be properly maintained and kept in good operating condition at all times.

3. Within ~~90~~ 60 calendar days of initial operation, Pacesetter Systems shall conduct performance tests in accordance with SCAQMD test procedures and furnish the SCAQMD a written result of such performance tests within 30 days of testing. Written notice of the performance tests shall be provided to the SCAQMD 7 days prior to testing so that an observer may be present. A proposal of source testing and analytical methods to be used shall be submitted in writing to the SCAQMD for approval at least 60 prior to testing.

   The performance tests shall consist of, but may not be limited to, a test of the inlet and exit streams to the abator system for:

   A. Ethylene oxide in ppm and lbs/hr.
   B. Destruction efficiency.
   C. Flow rate.

   The performance tests shall be conducted under maximum loading conditions of the sterilizers. In addition, the usage rates of ethylene oxide shall be recorded, and the abator temperature monitored during the tests.

4. The abator shall be equipped with a gage to verify the catalytic bed temperature is at least 300 degrees Fahrenheit during the operation of the system.

South Coast
AIR QUALITY MANAGEMENT DISTRICT
9150 FLAIR DRIVE, EL MONTE, CA 91731 (818) 572-6200

DATE: 5-15-91

PACESETTER SYSTEMS, INC
12 BBY BRADLEY AVENUE
SYLMAR CA. 91342

ATTENTION: MR. Stephen R. Walters

The South Coast Air Quality Management District has received your applications and made the following determination:

Appl. No.	Determination Number	Equipment Description
247254	(2)	ETHYLENE OXIDE STERILIZER NO. 1
247255	(2)	ETHYLENE OXIDE STERILIZER NO. 2
247256	(2)	ETO CATALYTIC INCINERATOR

TO BE LOCATED AT 15900 VALLEY VIEW COURT
SYLMAR CA 91342

Deter. No.

(1) The information you submitted with this application or in your latest submittal is complete; however, some clarifying data may still be needed. The acceptance of your application as complete indicates that sufficient information is on file to begin an evaluation, but does not imply that a permit has been approved.

(2) The information you submitted with this application or in your latest submittal, is NOT complete. Specific details of the information required to process your application are enclosed. Please submit the requested information by the date shown on the attached form.

(3) The information submitted with this application is not complete. Additional information was previously requested per District letter dated _____ (copy attached). If specific detailed information as outlined on the attached Additional Information Request Sheet is not submitted by _____, your application may be denied pursuant to Rule 210.

If you have any questions concerning your application, please contact MILTON CAHEN at (818) 572-6229.

Very truly yours,

Milton Cahen

for Dave Schwien
Senior Engineering Manager

MN:ai

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

MEMORANDUM

DATE: 5-15-91

TO: MR. STEPHEN R. WALTERS, AQC INC.

FROM: MILTON COHEN, SCAQMD

SUBJECT: ADDITIONAL INFORMATION REQUIRED IN REGARD TO PALESETTEN SYSTEMS, INC.

AS PER TELEPHONE CONVERSATION ON 5-15-91 PLEASE SUBMIT THE FOLLOWING:

1. DIMENSIONS OF THE CATALYTIC BED
2. CHEMICAL COMPOSITION OF CATALYTIC BED.
3. MATERIAL COMPOSITION OF STERILIZED PRODUCT AND PACKAGING.
4. STERILIZED PRODUCT AERATION ROOM, DETAILS AND OPERATION, PROVIDED SUCH ROOM IS REQUIRED.
5. INDICATE MAXIMUM NUMBER OF CYCLES ANY ONE STERILIZER WILL OPERATE IN ANY ONE DAY.
6. STATE THE INSTALLATION AND OPERATIONAL STATUS OF AN INDICATED THIRD (30 CUBIC FOOT) STERILIZER.

IF

PRE-SCREENING FEE ASSESSMENT SHEET

Company Name : Pacesetter Systems Inc Small Business ? ____ Yes ✓ No

	Unit No.	Equipment Description (BCAT or CCAT)	Appl Type	Mult Equip (√)	50% Penal (√)	Fee	Comment
1	7	000289	10			1700	
2	7	000287	10			1700	
3	7	06	10			3700	
4							
5							
6							
7							
8							
9							
10							
				TOTAL		7100	

Application Type :		50% Penalty Fee
10	P/C (New Construction)	No
15	Banking (ERC)	No
20	P/O (Equip did not need P/C)	No
25	Plan	No
30	P/O no P/C	Yes
40	Change of Ownership	No
50	Alter/Mod - Class I	No
	Class III	Yes
60	Change of Condition	No

REVIEWED BY: Rhett UNIT #: 7
Date Reviewed: 4-14-91 Ext #: 6260

AIR
QUALITY
CONSULTANTS

Air Quality Consultants, Inc.
15541 Commerce Lane
Huntington Beach, CA 92649

TEL: (714) 894-5252
FAX: (714) 893-2322

April 10, 1991

South Coast Air Quality Management District
9150 Flair Drive
El Monte, CA 91731

Re: Two Sterilizers and One Abator System Permit Application for
Pacesetter Systems, Inc.
12884 Bradley Avenue
Sylmar, CA 91342

Dear Air Quality Engineer:

Pacesetter Systems manufactures heart pacemakers and is relocating their operation to a new facility site in the same sensitive zone at 15900 Valley View Court, Sylmar. At this facility, there will be a fire proof sterilization room suited for two ethylene oxide (EtO) sterilizers with chamber volumes of 69 and 32 cubic feet. In compliance with the most current rule 1405, Pacesetter will utilize non-CFC base EtO (100% EtO). In addition, all sterilizer emissions and sterilization room air will be vented to a manufacturer guaranteed 99.9% efficient catalytic abator system. This abator system will run continuously, while the sterilizers operate on alternating days throughout the 5 day business week. The EtO usage is projected to be 5.65 pounds per day. After control, this amounts to a maximum of 0.0057 pounds of emission on any given day.

The enclosed application package contains all the necessary information and fees to process the permits. Pacesetter Systems wishes to begin full operation by June 1, 1991, so any effort to expedite the issuance of the Permits to Construct will be appreciated. Please do not hesitate to call with any questions.

Sincerely,

Steve R. Walters

Steve Walters
Environmental Engineer

cc: file

Pacesetter Systems, Inc.

Sterilizer #1 Permit Application Supplemental

1. Equipment Location Drawings: Refer to Attachment #1

2. Equipment Description:
   Ethylene Oxide Sterilizer #1, Getinge Model 8440AR1,
   35" x 57" x 60" chamber

3. Process Description:
   Batch loads of pacemakers and accesories are placed inside a vacuum chamber and experience a 22 hour sterilization cycle:

   a. The load is heated by recirculating the chamber air for a pre-set time period of 20 minutes.

   b. The chamber is evacuated by the vacuum pump at a pre-set rate until a pre-set vacuum level is achieved.

   c. The chamber is held under vacuum for 10 minutes to determine if any leaks exist.

   d. Compressed nitrogen gas is admitted to the chamber at a pre-set pressure. Chamber is re-evacuated, and charged again with nitrogen gas for a pre-set number of pulses.

   e. The load is humidified with pulse injections of steam to a pre-set absolute pressure level.

   f. The load is held at temperature and humidity for a pre-selected pre-conditioning time.

   g. Ethylene oxide (EtO) gas is admitted to the chamber at a pre-set rate until a pre-set pressure is achieved. Nitrogen gas is admitted to chamber at a pre-set rate until a pre-set pressure is achieved. A subsequent charge of nitrogen gas into chamber purges gas lines of EtO.

   h. Chamber pressure is maintained for the pre-selected sterilizing time period.

i. Chamber gases are exhausted through the ventilation system at a pre-set rate to an abator (a catalytic control device) where 99.9% of EtO is oxidized to carbon dioxide and water.

j. Chamber is evacuated to pre-set vacuum level. Nitrogen gas is admitted to chamber at a pre-set rate until pre-set pressure is attained (Steps i & j are repeated at least 2 additional times).

k. Complete chamber aeration commences by alternating a pre-set number of vacuum and air purges.

l. Air is admitted to the chamber through the bacterial retentive air filter until ambient atmospheric pressure is achieved.

4. Operating Schedule:
Cycle run time of each load is approximately 22 hours; estimate hours for EtO stage is 2 hours.

5. Process Rate:
Nitrogen and EtO gas flow rates are to be determined as appropriate for specific loads.

6. Fuels and Burners Used: N/A

7. Flow Diagram: N/A

8. Equipment Drawings: Refer to Attachment #2

9. Emissions Data:
All EtO emissions from sterilizer and sterilization room are vented to abator. 99.9% of EtO is oxidized to carbon dioxide and water.

10. Air Quality Impact: Risk Screening Analysis

Eqn (1) $MICR = Q \times (X/Q) \times U \times MP$

MICR - Maximum Individual Cancer Risk
Q - Emission Rate of EtO in lb/day
X/Q - EtO Concentration (Tables 3 & 4, Rule 1401)
U - Unit Risk Factor for EtO (Table 1, Rule 1401)
MP - Mutiple Pathway Adjustment Factor

Pacesetter Systems, Inc.

Calculations -

Q = EtO Usage x (1-abator efficiency)
= 1475 lb/year x 0.1%
= 1.475 lb/year x (1 year/261 days)
= 0.0057 lb/day of EtO emission

X/Q = 3.01 [ug/m3] / [lb/day]

U = 0.000088 [1/(ug/m3)]

MP = 1

MICR = 0.0057 x 3.01 x 0.000088 x 1
= 0.000001
= 1 in one million

Note - the Q value is the projected maximum emission from this facility on any given day given the sterilizers operate on alternate days. Same calculation appears on Sterilizer #2 Supplemental.

NO NEW SOURCE RECORDS FOR THIS CO ID
ENG930 EMISSION THRESHOLD / NEWSOURCE

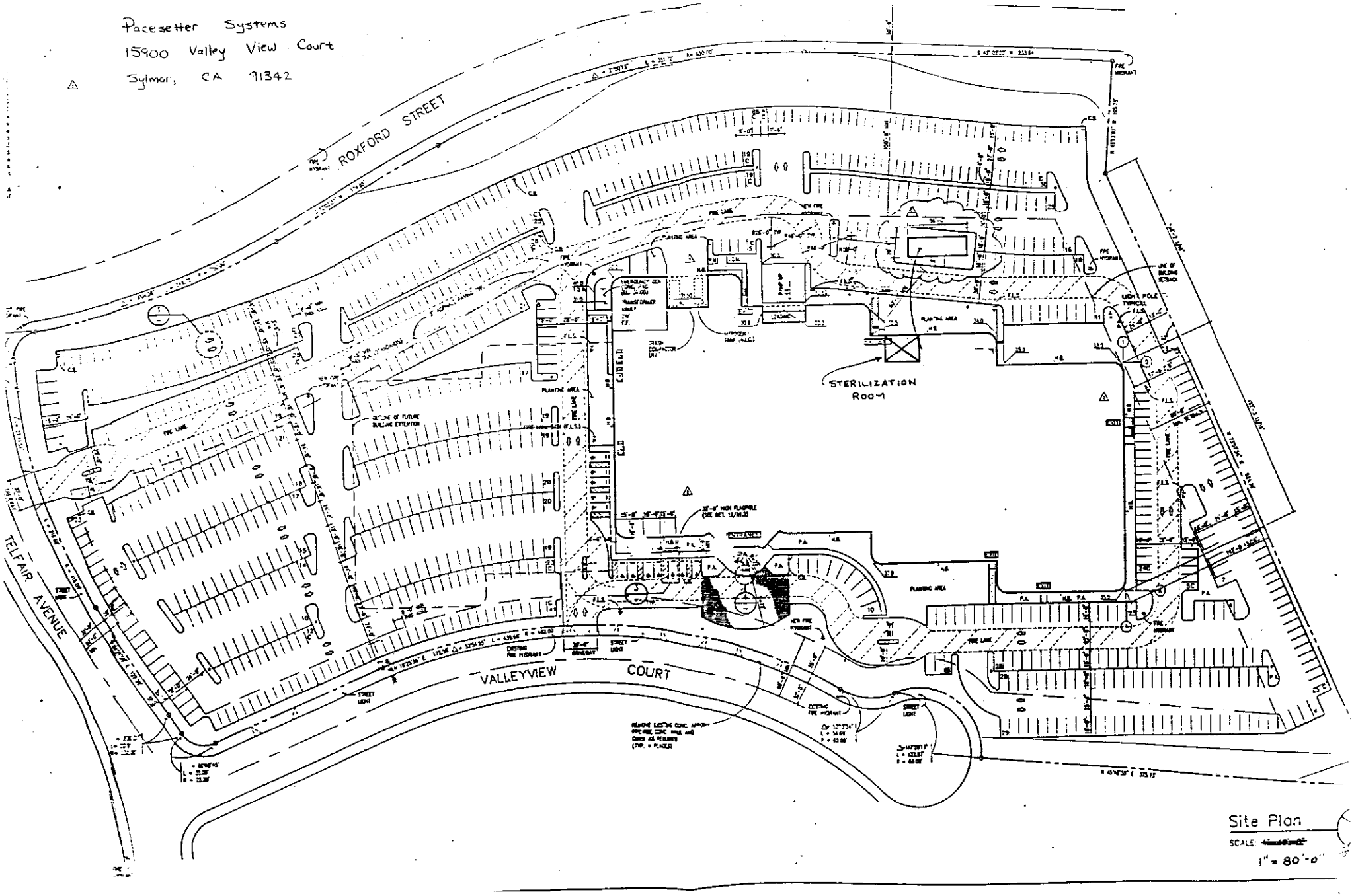
name: PACESETTER SYSTEMS INC company id: 085085
address: 15900 VALLEY VIEW CT date: 04/18/91
city: SYLMAR user: NS37

INCREASE (+) DECREASE (-) SUBSEQUENT TO 10-8-76

L#	I	M	date	appl	13 p/o rl	RHC #/day	NOX #/day	SO2 #/day	CO #/day	PART #/day	LEAD #/day	UNRHC #/day

f1 f2 f3 f4 CN CONTINUE REFRESH f7 MAIN

Pacesetter Systems
15900 Valley View Court
Sylmar, CA 91342



Site Plan

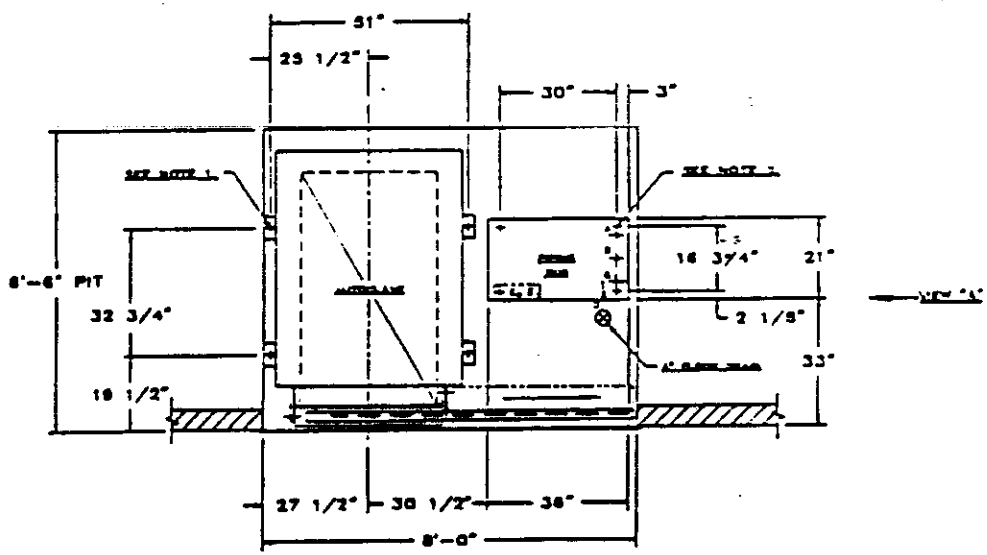
SCALE: ~~1/16"=1'-0"~~

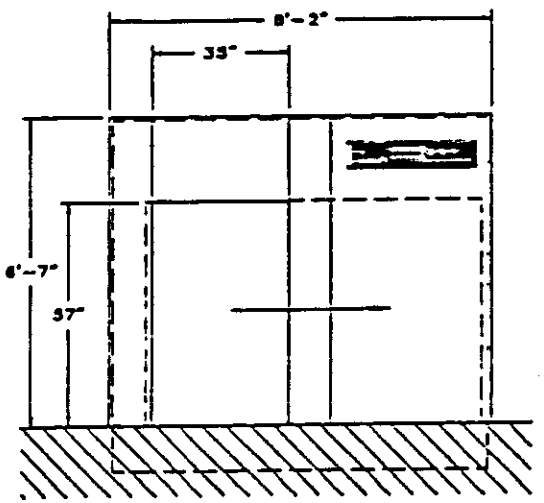
1" = 80'-0"

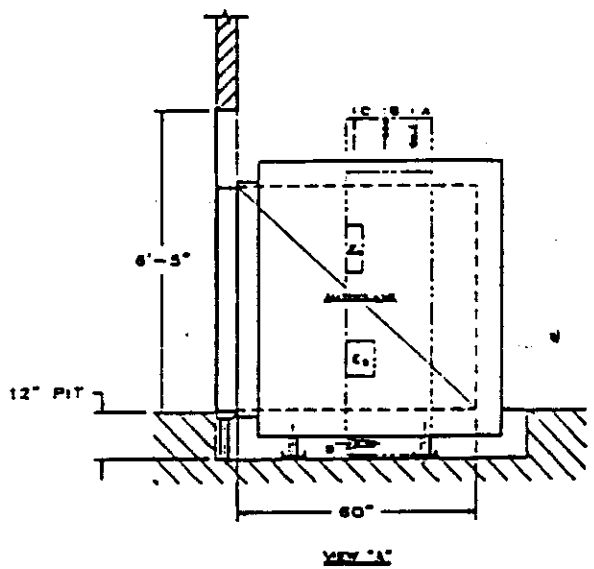
ATTACHMENT #2

4444-S80-05	A

SERVICE REQUIREMENTS		
A	STEAM	550 LB/HR MAX. 60-80 PSIG 1 1/2" NPT
B	COLD WATER	20 GPM MAX. <60°F 40-60 PSIG 1" NPT
C	COMP. AIR	3 SCFM MAX. 80-100 PSIG 3/8" NPT
D	DRAIN	1 1/2" NPT
E_1	ELECTRIC CONTROL	120V,1PH,60HZ,5A.
E_2	ELECTRIC POWER	208V,3PH,60HZ,13A. 240V,3PH,60HZ,11.8A. 480V,3PH,60HZ,5.9A.







VIEW "A"

NOTES

1. If Seismic Restraints are required, (4)3/4"UNCx8"Lg. SA325 Bolts should be secured (by others) to the floor, through the 7/8" Dia. holes provided in the frame at the indicated locations; suitable anchors must be provided and installed (b/o) to satisfy the following strength requirements:
   MAX. TENSILE LOAD (per bolt/anchor)= 2845 Lb.
   MAX. SHEAR LOAD (per bolt/anchor)= 2586 Lb.
2. If Seismic Restraints are required, (4)1/2"-13UNCx8"Lg. SA325 Bolts should be secured (by others) to the floor, through the 1" NPT pipe stubs provided on the frame at the indicated locations; suitable anchors must be provided and installed (b/o) to satisfy the following strength requirements:
   MAX. TENSILE LOAD (per bolt/anchor)= 1968 Lb.
   MAX. SHEAR LOAD (per bolt/anchor)= 758 Lb.

GETINGE INTERNATIONAL INC.
1100 TOWBIN AVE., LAKEWOOD, NJ 08701

CUTSHEET 35"x57"x60"
AR1 HI/VAC STERILIZER

SEISMIC RESTRAINTS

C	4444-S80-05	A